DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-850/S-011

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Brian A. Walter, Ph.D.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

Dear Dr. Walter:

Please refer to your supplemental new drug application dated January 6, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MICARDIS (telmisartan) 20, 40, and 80 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for electronic final printed labeling (FPL) revised as follows:

1. Under **DESCRIPTION,** 2nd paragraph, the first sentence that reads "Telmisartan is a white or slightly yellow crystalline substance" has been changed to:

   Telmisartan is a white to slightly yellowish solid.

2. Under **ADVERSE REACTIONS,** last paragraph, the sentence "In post-marketing experience, additional cases of angioedema and urticaria have been noted" has been deleted and this event information has been relocated to a new **Post-Marketing Experience** subsection (see below).

3. Under **ADVERSE REACTIONS**, a new **Post-Marketing Experience** subsection has been added that reads as follows:

   Post-Marketing Experience

   The following adverse reactions have been identified during post-approval use of MICARDIS tablets. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Decisions to include these reactions in labeling are typically based on one or more of the following factors: (1) seriousness of the reaction, (2) frequency of reporting, or (3) strength of causal connection to MICARDIS tablets. The most frequently spontaneously reported events include: headache, dizziness, asthenia, coughing, nausea, fatigue, weakness, edema, face edema, lower limb edema, angioneurotic edema, urticaria, hypersensitivity, sweating increased, erythema, chest pain, atrial fibrillation, congestive heart failure, myocardial infarction, blood pressure increased, hypertension aggravated, hypotension (including postural

hypotension), hyperkalemia, syncope, dyspepsia, diarrhea, pain, urinary tract infection, erectile dysfunction, back pain, abdominal pain, muscle cramps (including leg cramps), and myalgia.

Rare cases of rhabdomyolosis have been reported in patients receiving angiotensin II receptor blockers including MICARDIS.
NOTE: Please correct the spelling of "rhabdomyolisis" in the above sentence to "rhabdomyolysis".

4. Under **HOW SUPPLIED**, 1st sentence, the words "or off-white" have been added so this sentence now reads as follows:

   MICARDIS (telmisartan) is available as white or off-white, uncoated tablets containing telmisartan 20 mg, 40 mg or 80 mg.

5. The word "telmisartan" has been added throughout the labeling after the tradename MICARDIS for consistency with other Boehringer Ingelheim package inserts.

We have completed our review of this supplemental new drug application It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (package insert included in your submission of January 6, 2004).

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5332

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Doug Throckmorton
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